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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,865	06/07/2007	Ashok Saluja	07917-251US1	3834
26161 7590 10/12/2011 FISH & RICHARDSON P.C. (BO) P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER BURKHART, MICHAEL D				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
10/12/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

# Office Action Summary

**Application No.**

10/579,865

**Applicant(s)**

SALUJA ET AL.

**Examiner**

MICHAEL BURKHART

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5) ☒ Claim(s) 1-24 is/are pending in the application.
- 5a) Of the above claim(s) 5-7, 9-24 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-4 and 8 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 18 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-GB/US)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Page No(s)/Mail Date 9/11/08; 6/24/11

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 6/24/2011 is acknowledged. The traversal is on the ground(s) that claims 9-24 are simply further steps used in the methods of claim 1, and thus do not represent an undue burden on the Examiner. Applicants also assert that Mansell et al do not teach that TLR4 plays a role in pancreatitis, therefore the technical feature linking the inventions is not taught by the prior art. This is not found persuasive because this is a 35 USC 371 application, thus, search and examination burden is not a consideration for restriction purposes. Rather, as set forth in the Restriction Requirement, the claims do not share a special technical feature. Regarding Mansell et al, the role of TLR4 in pancreatitis is not given any patentable weight for reason of record and for reasons set forth below. The claims do not require any limitations, or prior knowledge, regarding the role of TLR4 in pancreatitis.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-7 and 9 - 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/24/2011.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mansell et al (FEBS letters, 2001, of record).

The instant claims recite an intended use for any candidate agent identified via the method steps, i.e. the phrase “for use in the treatment of acute pancreatitis” as found in the preamble of claim 1. This intended use limitation is not afforded any patentable weight, as the treatment of pancreatitis is not recited as an active method step, and any agent identified via the claimed methods would meet the intended use as a “candidate agent” for pancreatitis therapy.

If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997), (MPEP 2111.02).

Mansell et al teach cells expressing TLR4 (THP-1 and HEK 293) that are treated with the serpin antithrombin III and hirudin. The cells are then assayed for an activity of TLR4 (NF- $\kappa$ B activation). See the abstract, page 313, second column, second full ¶, and Fig. 4 on page 315 in particular. Absent any limiting definition in the specification, the phrase “by reducing a level of TLR4 protein” in claim 2 is interpreted in this instance to comprise reducing a level of active TLR4 protein.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Karras et al (US 20030125272 A1, 7/3/2003, e.f.d. 11/19/2001, newly cited).

The instant claims recite an intended use for any candidate agent identified via the method steps, i.e. the phrase “for use in the treatment of acute pancreatitis” as found in the preamble of claim 1. This intended use limitation is not afforded any patentable weight, as the treatment of pancreatitis is not recited as an active method step, and any agent identified via the claimed methods would meet the intended use as a “candidate agent” for pancreatitis therapy.

If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997), (MPEP 2111.02).

Karras et al teach methods for inhibiting the activity and expression of TLR4 using antisense RNA or siRNA. Cells expressing TLR4 are contacted with various antisense oligonucleotides, then evaluated for TLR4 mRNA inhibition and expression (considered to be transcription and/or translation as recited by instant claims 3 and 4). See in particular Examples 10 – 15, beginning with ¶ [0237].

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/  
Primary Examiner, Art Unit 1633